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EXAMINER

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| 1812 | 11 |

11/14/96

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

**Part II SUMMARY OF ACTION**

1. ☒ Claims 19-21, 24 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-18, 22-23 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 19-21, 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

]1. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2-3, 7 and 9 recite the broad recitation for R2 as being optionally present, and the claims also recite limitations for when R2 can be other alternatives which is the narrower statement of the range/limitation.

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite and confusing when defining R2 and/or R3, nor is it clear from the manner in which the claim is written whether the recited sequences that follows R3 is suppose to

be R3. It would appear that there may be two definitions for R3. The claim needs to be rewritten to clarify the meaning.

3. Claims 1, 7-16, 17-18 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the full length DNA sequence, and certain specifically modified DNA sequences, does not reasonably provide enablement for (a) any fragment of a DNA coding for a TNF receptor (as in claim 1), or for any fragment of the formula in claim 1(at the end), or a fragment of the sequence of claim 2 (as defined in claim 9); or (b) for NA which hybridize under low stringency conditions as in claim 7; or (c) to any DNA that encodes for a TNF binding protein or it's functional derivative as set forth in claim 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or how to both make and use the invention commensurate in scope with these claims.

There are various aspects of this scope rejection, which have been enumerated above with specific claim designations that will be discussed individually as enumerated above (e.g. as a---->d).

a) With regard to "fragment", the specification does provide enablement in the form of how to use the full scope of such. The Examiner concedes that there is probably limited enablement for certain DNA fragments that could be as probes (see page 21 of the specification); however, this is a relative term with a non-specific and unqualified meaning. It is well known that in order

to be used as a probe, the fragment must be of a sufficient length and must correspond to a particular region and be of a certain specificity. Applicants claims read on one or up to eight nucleotides, however, it is also well known that short pieces of nucleic acids are not useful as probes-even under high stringency. Further, such short nucleic acid pieces would tend to non-specifically hybridize to other sequences that are not specific to TNF receptors (R) or binding protein(BP). In view of this, the skilled artisan would not know how to use the full scope of such fragment, and would thus have to resort to undue experimentation. This applies to claims 1, 8-10, 17.

b) The specification is also not enabled relative to how to both make and use nucleic acid hybridization condition at low stringency. "Low" is a relative term and does not serve to sufficiently define and enable the nature of the conditions of hybridization that would be considered "low stringency". Furthermore, applicant's specification fails to define the metes and bounds, as well as the scope of such. In the absence of a clear definition for such, and further in the absence of sufficient examples or guidance, the skilled artisan would have to resort to undue experimentation in order to practice the scope of the claims. This is further supported by the prior art to Anderson et al (1985), which teach that low stringency produces poor matches and is insufficient to distinguish between distantly-related members of a family of sequences (it thus yields unrelated and undesired sequences relative to the encoded protein of interest). The skilled

artisan would not know how to use such non-specific and non-related sequences that would ultimately result from low stringency. This applies to claim 7.

c) The specification is also not enabled for how to both make and use any DNA that encodes for a TNF binding protein or it's functional derivative as set forth in claim 13. First of all, the specification is not enabled for any TNF binding protein. At the time of applicants invention it was known that there were multiple TNF BP (e. g. TNF-BP I and TNF-BP II, as well as other protein such as inhibitors that were considered TNF-BP. These various TNF BP share little or no structural similarity and possess distinct functional activity, thus, one is not predictive from the other. Applicants specification is only enabling for a TNF-BP that has the NA or AA of that as shown in claims 1 or 2 (now known as p55 or the low affinity TNF receptor). The other aspect of this part of the scope rejection is that there is also insufficient enabled for the full scope of DNA that would encode "any functional derivative". While there are many protein that function in the same or similar manner, the sequence for one is not always predictive of the sequence for another encoded protein that would function similarly. Thus, the skilled artisan would have to resort to undue experimentation by way of trail and error in order to make and use the full scope of such. This applies to claims 13-16, 18 and 23.

d) The specification is also not enabled for any and all DNA sequences-particularly those that are merely designated by the alphabetical designation as set forth in claims 11-12 and 14-16. This designation is insufficient to define or characterize the DNA sequence that is intended or

encompassed by such; nor is the full scope of that this/these DNA sequences cover enabled by the specification. Amending the claims to refer to a deposit number, or some other specific feature/characteristic would obviate this aspect of the rejection.

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 2-6, 11-12, 17, ans 7, 9-10, 14, 18 and 23 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2-7, 9-12, 14, 17-18 and 22-23 of copending Application No. 08/383676. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

It is pointed out that claims 7, 9-10, 14, 18 and 23 are included in this provisional double patenting rejection even though these claims have been slightly amended in S. N. 08/383676. However, such amendments are of a minor nature and do not serve to distinguish these claims from the instant claims. Thus, these claims are properly rejected under a provisional statutory double patenting rejection, but in the event that these claims are not view as being the same under 35 USC 101 for double patenting, then claims 7, 9-10, 14, 18 and 23 would be obvious over these claims in S.N. 383676 as set forth hereinbelow.

Claims 2-6, 11-12, 17 ans 7, 9-10, 14, 18 and 23, directed to an invention not patentably distinct from claims 2-7, 9-12, 14, 17-18 and 23 of commonly assigned S.N. 383676.

Specifically, claims 2-6, 11-12, and 17 read verbatim in both applications. Relative to claims 7, 9-10, 14, 18 and 22-23, which have been amended in S.N. 383676, these changes are of a minor nature and do not serve to distinguish the inventive concept; alternative, if they are distinct, then such claims would represent an obviousness double patenting rejection for the following reasons.

5. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7, 9-10, 14, 18, and 23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 9-10, 14, 18 and 22-23 of copending Application No. 08/383676. Although the conflicting claims are not identical, they are not patentably distinct from each other because the slight amendment to the claims in S.N. 383676 are of a minor nature and would not serve to distinguish these claims. However, in the event they are of a different scope, then the instant claims are generic to the claims of 383676, and are still obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 7-9, 11-16 , 18 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Smith et al (`760),

These claims are being rejected in view of the broad claim's language for "fragment", nucleic acid that will hybridize under low stringency, and in view of the broad designation for the DNA as set forth in claims 11-12, 13-14, 18 and 23. The prior art disclose the DNA for a TNF receptor that would be expected to possess a "fragment" of the sequence for the instant TNF R or TNF-BP and that would also hybridize to such under low stringency based on their limited sequence identity. The encoded protein was expressed in both prokaryotes and eukaryotes. See the entire document.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallach et al (`378) .

The prior disclose a protein that binds to TNF and sets forth a partial N-terminal amino acid sequence that is consistent with the full length encoded sequence of the instant application ( see page 3). It is pointed out that at page 9, lines 20-23 of the instant specification, applicants admit that the instant protein and the protein of the prior art are identical. The prior art fails to expressly set forth the DNA sequence of the TNF R/TNF BP; however at pages 8-11 Wallach et al disclose specific processes/procedures for obtaining the DNA. Based on these teaching, at the time of the invention it would have been prima facie obvious to follow these processes in order to obtain the complete invention as claimed (also see the claims).

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any other prior art is cited as of interest to show related art.

9. Any inquiry concerning this communication should be directed to Garnette D. Draper at telephone number (703) 308-4232.

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800